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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,049	06/22/2001	Yasuki Kato	506.40278X00	1134

7590 02/06/2006

Antonelli Terry Stout & Kraus
1300 North Seventeenth Street Suite 1800
Arlington, VA 22209

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
09/869,049	22 June 2001	Y. Kato et al.	506.40278X00

EXAMINER
Kailash C. Srivastava, Ph.D.

ART UNIT	PAPER
1655	0060131

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

1. Applicants' Post-allowance communication filed 20 January 2006 is received. The Examiner appreciates the compliments from applicants' representative. The applicants' representative went beyond the call of duty in making such gracious kind remarks.

2. The claims, referred to as Examiner's amendment accompanying said communication have, however, not been entered. This is because said claims are part of the Notice of Allowability (see Pages 3-8 enclosed with Notice of Allowability) mailed 05 January 2006.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1655
(571) 272-0923

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200

31 January 2006

Examiner's Amendment

8. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 CFR §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

9. Authorization for this Examiner's amendment was given in a telephone interview with Mr. William I. Solomon on 9 December 2005.

In the Claims:

- Cancel Claims 1, 4, 21, and 81-98:
- Add new Claims 99-119 as follows:

Not entered because these claims are already the subject of the enclosed Notice of Allowance mailed on 1/5/2006 1/31/2006

99. (New) A pharmaceutical preparation comprising a compound (I), which is obtained by reacting a peptide (II) having a free amino group, with a sugar (III) having reducing power and selected from group A, wherein said peptide is a pharmaceutical compound,

wherein group A consists of lactose, sialyllactose and compounds prepared by chemically binding a polymer from the group consisting of polyoxyethylene, polyglutamic acid and polyvinylpyrrolidone to a hydroxyl group other than the hydroxyl group formed from the reducing aldehyde group of lactose and sialyllactose,

wherein an amino group of said peptide (II) reacts with an aldehyde group in said sugar (III); and

wherein said compound (I) can release said peptide (II) having a free amino group in response to changes in pH.

100. (New) The preparation according to claim 99, wherein said peptide (II) is insulin.

101. (New) The preparation according to claim 99, wherein said peptide (II) is enkephalin.

102. (New) The preparation according to claim 99, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

said peptide (II) is combined with a pharmaceutical carrier, to obtain a peptide-carrier composition, and said peptide-carrier composition is reacted with said sugar (III) to give said preparation comprising said compound (I).

103 (New) The preparation according to claim 99, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

said peptide (II) is reacted with said sugar (III) to give said compound (I), and said compound (I) is combined with a pharmaceutical carrier.

104. (New) The preparation according to claim 99, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

said peptide (II) and said sugar (III) are encapsulated in a pharmaceutical carrier, and said peptide (II) is reacted with said sugar (III) to give said compound

Not entered because these claims are already enclosed with the notice of allowability mailed 5 January 2006
1/31/2006

(I) in said pharmaceutical carrier.

105. (New) The preparation according to claim 99, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

said peptide (II) is reacted with said sugar (III) to give said compound (I), and said compound (I) is encapsulated in said pharmaceutical carrier.

106. (New) The preparation according to any one of claims 102-105, wherein said pharmaceutical carrier is selected from the group consisting of liposome, lipid emulsion, microemulsion, polymer micelle, microcapsule, microsphere and magnetic particles.

107. (New) The preparation according to claim 99, wherein said group A consists of lactose and sialyllactose.

108. (New) The preparation according to any one of claims 102-105, wherein said group A consists of lactose and sialyllactose.

109. (New) The preparation according to claim 106, wherein said group A consists of lactose and sialyllactose.

110. (New) The preparation according to claim 100, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

insulin is combined with a pharmaceutical carrier, to obtain an insulin-carrier composition, and said insulin-carrier composition is reacted with said

Not entered because claims are already enclosed with the Notice of Allowance mailed 01/5/2006
JK 1/31/2006

sugar (III) to give said preparation comprising said compound (I).

111. (New) The preparation according to claim 100, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

insulin is reacted with said sugar (III) to give said compound (I), and said compound (I) is combined with a pharmaceutical carrier.

112. (New) The preparation according to claim 100, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

insulin and said sugar (III) are encapsulated in a pharmaceutical carrier, and said insulin is reacted with said sugar (III) to give said compound (I) in said pharmaceutical carrier.

113. (New) The preparation according to claim 100, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

insulin is reacted with said sugar (III) to give said compound (I), and said compound (I) is encapsulated in said pharmaceutical carrier.

114. (New) The preparation according to any one of claims 110-113, wherein said pharmaceutical carrier is selected from the group consisting of liposome, lipid emulsion, microemulsion, polymer micelle, microcapsule, microsphere and magnetic particles.

115. (New) The preparation according to claim 101, wherein said compound (I)

Not entered because these claims were already enclosed with the Notice of Allowability mailed 01/05/2006
1/31/2006

is in a pharmaceutical carrier obtained by the following steps:

enkephalin is combined with a pharmaceutical carrier, to obtain an enkephalin-carrier composition, and said enkephalin-carrier composition is reacted with said sugar (III) to give said preparation comprising said compound (I).

116. (New) The preparation according to claim 101, wherein said compound (I) is in a pharmaceutical carrier obtained by the following steps:

enkephalin is reacted with said sugar (III) to give said compound (I), and said compound (I) is combined with a pharmaceutical carrier.

117. (New) The preparation according to claim 101, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

enkephalin and said sugar (III) are encapsulated in a pharmaceutical carrier, and said enkephalin is reacted with said sugar (III) to give said compound (I) in said pharmaceutical carrier.

118. (New) The preparation according to claim 101, wherein said compound (I) is encapsulated in a pharmaceutical carrier obtained by the following steps:

enkephalin is reacted with said sugar (III) to give said compound (I), and said compound (I) is encapsulated in said pharmaceutical carrier.

119. (New) The preparation according to any one of claims 115-118, wherein said pharmaceutical carrier is selected from the group consisting of liposome,

Not entered because these claims were already enclosed with the Notice of Allowability mailed 1/25/06

1/31/2006

lipid emulsion, microemulsion, polymer micelle, microcapsule, microsphere and magnetic particles.

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Examiner's Statement of Reasons for Allowance

10. The following is Examiner's statement of reasons for allowance:

The closest prior art are:

Sessler et al. (U.S. Patent 5,580,543);

Katsukiyo (JP-07-061999); and

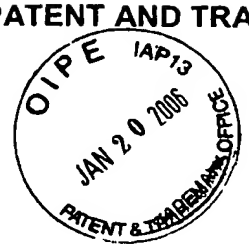
Masashi et al (JP 9-263579).

The presently claimed invention comprising a pharmaceutical composition produced via reacting a peptide having a free amino group with lactose or sialyl lactose or compounds wherein lactose or sialyl lactose are chemically bound to a polymer among polyoxyethylene, polyglutamic acid, and polyvinylpyrrolidone via the hydroxyl group other than the hydroxyl group formed from the reducing aldehyde group of lactose or sialyllactose is not taught by any of the references cited *supra* either individually or in combination.

Thus, none of the art cited *supra* alone or in combination teach or reasonably suggest to obtain a pharmaceutical composition produced via reacting a peptide having a free amino group with lactose or sialyl lactose or compounds wherein lactose or sialyl lactose are either chemically bound to a polymer among those recited in the claimed invention, or lactose or sialyllactose are bound to said polymers according to the method recited in the claimed invention.

506.40278X00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



FWDX 1/26/2006

Applicant:	Y. KATO, et al.
Serial No:	09/869,049
Filed:	JUNE 22, 2001
Title:	MEDICINAL PREPARATIONS (as amended)
Group:	1655
Examiner:	Kailash C. Srivastava
Confirm. No.:	1134
Allowed:	JANUARY 5, 2006

STATEMENT OF SUBSTANCE OF INTERVIEW

Mail Stop: ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

January 20, 2006

Sir:

Appreciation is expressed to Examiner Srivastava for his courtesy during a telephone interview conducted between the Examiner and William I. Solomon on December 21, 2005, in connection with the above-identified application.

During the course of this telephone interview, Applicants' representative authorized the Examiner to cancel claims 1, 4, 21 and 81-98, and add new claims 99-119, by way of Examiner's Amendment (copy attached) to bring the above-identified application in better condition for allowance.

If the Examiner believes that there are any points which may be clarified or otherwise disposed of, either by telephone discussion or by personal interview, the Examiner is invited to contact Applicants' undersigned attorney at the number indicated below.

Please charge any shortage in fees due in connection with the filing of this paper to the Antonelli, Terry, Stout & Kraus, LLP Deposit Account, Deposit Account No. 01-2135 (Case No. 506.40278X00), and please credit any excess fees to such deposit account.

Respectfully submitted,

ANTONELLI, TERRY, STOUT & KRAUS, LLP

By _____
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Enclosure: Examiner's Amendment (6 pp.)

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